GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2240
ANSWERED ON:17.12.2003
CLEARANCE OF BIOTECHNOLOGY PRODUCT
GIRDHARI LAL BHARGAV

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the clearance of Drugs Controller General is required for the manufacture of any Recombinant Biotechnology Product that is likely to be introduced in India;

(b) if so, the criteria adopted for the clearance of such drugs alongwith the names of the companies that have applied for such clearance;

(c) whether a number of companies are manufacturing and marketing the products without the permission of Drug Controller;

(d) if so, the names of the companies found guilty during the last three years;

(e) whether the Drug Controller granted permission to Nova Nordisk for the manufacture of Recombinant insulin without undertaking clinical trials; and

(f) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) Yes, Sir. As per the modalities being normally followed, the indigenously developed DNA based products are initially examined by Recombinant Committee for Genetic Approval (RCGM) under the Department of Biotechnology.Based on the evaluation of all relevant data, RCGM advises the firms to approach DCG(I) to undertake human clinical trials of said drug.The clinical trial protocols are examined for granting necessary NOC by the office of DCG(I).After completion of clinical study, the report of the trial along with data on physicochemical and bio-chemical characterization, description of the target gene, sequencing of Amino acids, manufacturing/quality control etc., are examined by a multidisciplinary Expert Panel to decide about market authorization for such products. The facility provided by the applicant for manufacture of said product is also verified as per GMP norms through joint inspection carried out by the State and Central Drugs Control Officials. Unlike other pharmaceuticals, approval of Genetic Engineering Approval Committee (GEAC) under Ministry of Environment is required to import, manufacture and market Recombinant DNA Biotech Products.

Based on the above criteria office of Drugs Controller General (I) have cleared the following Recombinant DNA derived therapeutics.

1. r-hu alpha 2b intereferon of M/s Shantha Bio-tech Pvt. Ltd. Hyderabad.

2. r hu insulin and its analogue of M/s Wockhardt Ltd. Mumbai.

3. r DNA Streptokinase of M/s Bharat Biotech Int. Ltd. Hyderabad.

4. r DNA Streptokinase of M/s Shantha Biotech Pvt. Ltd. Hyderabad.

Applications have been received from the following companies who also intend to indigenously manufacture r DNA Bio-tech products in the country:

1. M/s Biocon India Limited, for r human insulin

2. M/s Instas Pharmaceuticals, Ahmedabad for r human Granulocytes Colony Stimulating Faftor (r GCSF)

3. M/s Bio Genomics Limited, Mumbai for r human Insulin

4. M/s Shantha Bio Techniques, Hyderabad for r human erythropoetin and r human Granulocyles Colony Stimulating Factor (r GCSF).

5. M/s Panacea Bio-tech Ltd. New Delhi for r human Anthrax vaccine.
6. M/s Wockhrdt Ltd. Mumbai for r human interferon alpha 2 b.

7 M/s Virchow Labs Ltd. Hyderabad for r human Platelets derived Growth factor r human interieukin and r human I Interleukin alpha 2b.

8. M/s Bharat Biotech Int. Ltd. Hyderabad for r human Epidermal Growth factor.

9. M/s Indian Immunologicals Ltd. Hyderabad for r DNA anti-rabies vaccine for Human and Veterinary use and r Hepatitis B vaccine.
10. M/s Bio E Ltd. Hyderabad, for r Hepatitis B vaccine.

(c) No, Sir.

(d) Question does not arise.

(e) & (f) M/s Novo nordisk is not indigenously manufacturing r Human Insulin.However, the firm has been permitted for its import in the country in the year 1994.